K071576

510(k) SUMMARY

Textronics, Inc.'s ECG Electrode

NOV - 2 2007

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Textronics, Inc.
3825 Lancaster Pike
Wilmington DE 19805

Phone: (302) 351-2162
Facsimile: (302) 998-7870

Contact Person: Michael McBrearty, Ph.D.

Date Prepared: May 31, 2007

Name of Device

Textronics™ ECG Electrode

Common or Usual Name

ECG Electrode

Classification Name

Electrode, Electrocardiograph

Predicate Devices

Unomedical 4560M Unilect Short Term ECG Electrodes (K944497)
Medi-Trace model 530 ECG Conductive Adhesive Electrodes (K945479)
Accuheart™ Electrode belt (K043361)

Intended Use / Indications for Use

The Textronics™ ECG Electrode is intended for use in general electrocardiograph monitoring and recording procedures.

The Textronics™ ECG Electrode is indicated for use with most ECG instruments on the market. It is indicated for applications including resting ECGs, exercise ECGs, and/or ambulatory monitoring. The device is indicated for both prescription and over-the-counter use.

Technological Characteristics

The Textronics™ ECG Electrode consists of electrodes, an exterior housing for the electrodes that makes contact with the patient, and a means of connecting the device to an ECG instrument. The Textronics™ ECG Electrode has textile–based electrodes made of electrically conductive yarns knitted together with electrically non-conductive yarns. The conductive yarns are silver coated polyamide (nylon). The non-conductive yarns can include cotton, spandex, polyester, and/or nylon. The Textronics™ ECG Electrode's textile-based electrodes have an exterior housing made of fabric, which can be made out of common textile materials, including polypropylene, nylon, Lycra® Spandex, polyester, and/or cotton. This fabric exterior housing can take the shape of a variety of garments, such as chest straps, wrist bands, shirts, bras, or vests. The Textronics™ ECG Electrode connects to ECG instruments via a conductive snap.

Performance Data

The Textronics™ ECG Electrode has been tested in the lab using ECG recording devices with the commercially available ECG electrodes and the Textronics™ ECG Electrode used simultaneously. ECGs were recorded, and the tracings were compared. In all instances, the Textronics™ ECG Electrode functioned as intended and the clarity and resolution of the tracings were observed to be substantially equivalent to the commercially available electrodes.

Substantial Equivalence

The Textronics™ ECG Electrode is substantially equivalent to several predicates, including the Unomedical 4560M Unilect Electrodes, the Medi-Trace model 530 ECG Conductive Electrodes and the Accuheart™ Electrode belt. The Textronics™ ECG Electrode has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Textronics™ ECG Electrode and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Textronics™ ECG Electrode performs very similarly to commercially available ECG electrodes. Thus, the Textronics™ ECG Electrode is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2007

Textronics Inc.
c/o Ms. Janice Hogan, Esq.
Hogan & Hartson, LLP
1835 Market Street, 28th Floor
Philadelphia, PA 19103

Re: K071576
Textronics™ ECG Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: October 242007
Received: October 24, 2007

Dear Ms. Hogan:

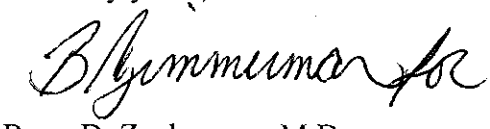
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K071576

Device Name: Textronics™ ECG Electrode

Indications for Use:

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The Textronics™ ECG Electrode is indicated for use with most ECG instruments on the market. It is indicated applications including resting ECGs, exercise ECGs, and/or ambulatory monitoring.

Prescription Use X (Part 21 C.F.R. 801 Subpart D)	AND/OR	Over-The-Counter X (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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ivision of Cardiovascular Devices
)10(k) Number K071576